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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,722	09/17/2003	George A. Cates	1038-1268 MIS	2228

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/663,722

Applicant(s)

CATES ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3, 4, 6-18, and 20 are pending and under consideration.
2. In the prior action, claims 1-20 were pending and rejected. In the amendment of December 19, 2006, the Applicant amended claims 1, 3, 4, 18, and 20; and cancelled claims 2, 5, and 19.

Specification

3. **(Prior Objection- Withdrawn)** The disclosure was objected to because of indicated informalities in pages 5 and 21. In view of the amendments to the specification, the objection is withdrawn.
4. **(Prior Objection- Maintained)** The use of the trademarks "Triton" and "Fluzone" have been noted in this application. In the present case, the provided generic language for the trade names "FLUZONE" and "TRITON X-100" are not sufficiently descriptive. It is suggested that the descriptors "FLUZONE split-antigen influenza vaccine" and "TRITON X-100 nonionic surfactant" be used.

Drawings

5. **(Prior Objection- Withdrawn)** The drawings were objected to because the drawing marked as Figure 1 appears to have indicated the claimed composition as "Flu/RSV + PCP." It appears that this should read - - Flu/RSV + PCPP- -. In view of the amendment to the drawings, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Withdrawn)** Claims 1-20 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions and methods of inducing an anti-RSV immune response in humans, does not reasonably provide enablement for compositions effective for conferring protection or methods of immunizing humans against RSV infection. In view of the amendments to the claims, the rejection is withdrawn.

8. **(Prior Rejection- Maintained)** Claim 4 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to compositions comprising any adjuvant or any inactivated influenza preparation with any mixture of the indicated RSV antigens such that the desired anti-RSV enhancement is achieved. The Applicant has amended the claims to provide further definition of the adjuvant, but not of the influenza preparation. Because insufficient descriptive support has been provided for the claimed genus of compositions comprising combinations of the indicated RSV antigens with any influenza antigen, and as no argument or amendment has been presented with respect to this portion of the rejection, the rejection is maintained for the reasons of record.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **(Prior Rejection- Withdrawn)** Claims 1-20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what was meant by an “immunoeffective amount.” In view of the amendment to the claims, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 1-16, 18, and 20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is withdrawn as the phrase “non-virulent influenza virus preparation” is read to include any non-virulent composition, whether the preparation is a whole virus or a subunit composition.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **(Prior Rejection- Maintained)** Claims 1-3, 6-19 were rejected under 35 U.S.C. 103(a) as being obvious over Cates et al. U.S. Patent 6,020,182 (Cates U.S.- of record in the April 2004 IDS), in view of Smith et al. (U.S. 5,762,939) and Webster et al. (U.S. 5,824,536). Claims 2 and 19 have been cancelled from the application. The rejection is therefore withdrawn from these claims.

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The Applicant traverses the rejection of the pending claims on two grounds. First, the Applicant asserts that there is no motivation for those of ordinary skill in the art to combine the RSV composition of Cates specifically with an anti-influenza composition. Second, the Applicant asserts that there would have been no reasonable expectation of success in the combination of the two combinations such that the immunogenicity of the RSV component would not be reduced. These arguments are not found persuasive.

With respect to the first argument in traversal, it was previously noted that the Cates reference specifically teaches the combination of the RSV composition with other vaccine compositions. Moreover, the reference identifies the influenza vaccine as one such composition for combination. Thus, it would have been obvious to those of ordinary skill in the art to have combined the RSV combination of Cates with any of the other vaccine compositions identified therein, including the influenza preparation. Because it would have been obvious from these teachings to combine the Cates RSV composition with an anti-influenza composition, it would have also been obvious to those of ordinary skill in the art to use the known influenza composition of Smith and Webster in that combination. (Contrary to the Applicant's assertion, the teachings of Webster were referred to in the first paragraph of page 12 in the prior action). Moreover, additional motivation for the combination was also noted on the paragraph spanning pages 12-13 of the prior action. In view of the above, including the specific suggestion by Cates to combine the RSV composition with other vaccines including an anti-influenza vaccine, the Applicant's first argument is not found persuasive.

The Applicant next asserts that there would not have been an expectation that formulating the influenza composition with the RSV preparation would not result in a lack of impairment of

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the immunogenicity of the individual components. This argument is not found persuasive for the reasons indicated on page 13 of the rejection. In view of these teachings in the art indicating that negative interactions among combined vaccines is rarely observed, and the suggestion in Cates that the described RSV composition may be combined with other vaccines, the Applicant's second argument in traversal is also not found persuasive.

The rejection is therefore maintained for the reasons above, and the reasons of record.

14. **(Prior Rejection- Maintained)** Claims 1-3, and 6-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al. ("Cates PCT," WO 98/02457- of record in the April 2004 IDS), in view of Smith (supra.) and Webster (supra). The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the rejection over Cates U.S. in view of Smith and Webster above. These arguments were not found persuasive for the reasons described above. The rejection is therefore maintained against pending claims 1, 3, and 6-18 for the reasons above and the reasons of record.

15. **(Prior Rejection- Maintained)** Claims 1-3, 5-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, in view of the teachings of Smith and Weber as applied to claims 1, 3, and 6-18 above, and further in view of Payne (Vaccine 16: 92-98). The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the rejection over Cates U.S. in view of Smith and Webster above. These arguments were not found persuasive for the reasons described above. The rejection is therefore maintained against pending claims 1, 3, and 6-18 for the reasons above and the reasons of record.

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16. **(Prior Rejection- Maintained)** Claims 1-3, and 6-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, as applied to claims 1, 3, and 6-18 above, and further in view of Huebner (U.S. Patent 5,612,037). The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the rejection over Cates U.S. in view of Smith and Webster above. These arguments were not found persuasive for the reasons described above. The rejection is therefore maintained against pending claims 1, 3, and 6-18 for the reasons above and the reasons of record.

17. **(Prior Rejection- Maintained)** Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, in view of Smith and Weber, or in view of Huebner, as applied above, and further in view of Potash (U.S. 5,911,998). The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the rejection over Cates U.S. in view of Smith and Webster above. These arguments were not found persuasive for the reasons described above. The rejection is therefore maintained against pending claims 1, 3, and 6-18 for the reasons above and the reasons of record.

Double Patenting

18. **(Prior Rejections- Maintained)** Claims 1-3 and 5-17 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either of claims 1-9, and 13 of U.S. Patent No. 6,020,182 (Cates, supra), in view of Smith, Webster, Payne, and Potash as described in the rejections of these claims under 35 U.S.C. 103(a) above; or

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of claims 1, 2, 6-16 of U.S. Patent No. 6,309,649, in view of Smith, Webster, and Payne. No arguments in traversal of these rejections have been presented. The rejection is therefore maintained against pending claims 1, 3, and 6-17 for the reasons above and the reasons of record.

19. **(Prior Rejections- Maintained)** Claims 1-3, 5-17 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, and 9-11 of copending Application No. 10/467828 in view of the teachings of Cates PCT, Smith, Webster, and Payne. Claims 1-3, 5-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2-7, 9, 12-21, 23, 24, and 36 of copending Application No. 10/488241 in view of the teachings of, Smith, Webster, and Payne, and Potash.

20. **(Prior Rejection- Maintained- Made Non-provisional)** Claims 1-20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-14, 20, and 21 of copending Application No. 09/868,177. This application has now been issued as U.S. Patent 7169395. The rejection is therefore made Non-provisional. The Applicant provides no argument in traversal of this rejection. It is therefore maintained over pending claims 1, 3, 4, 6-18, and 20.

Conclusion

21. No claims are allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

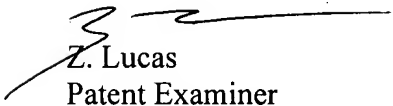
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

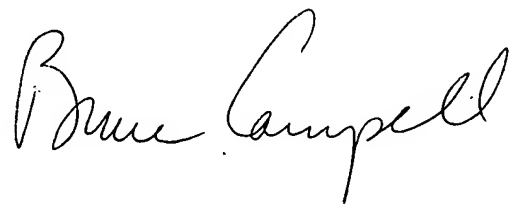
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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